DEVELOPING AN ANTICOAGULATION CLINIC

PRESENTED BY:

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UCONN SCHOOL OF PHARMACY

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FACULTY DISCLOSURE

DR. GALLI HAS NO FINANCIAL RELATIONSHIPS TO DISCLOSE

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LEARNING OBJECTIVES

At the conclusion of this activity, pharmacists will be able to:

- Discuss the benefits of establishing an anticoagulation clinic
- List the steps required to establish and run an anticoagulation clinic
- Describe the important aspects of operating an anticoagulation clinic
- Describe the financial considerations of running an anticoagulation clinic

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CASE STUDY

You have been approached by the lead cardiologist of a community teaching hospital affiliated with an on-site cardiology clinic. To date, a nurse has managed all their warfarin patients amidst her other duties and is asking for help.

- RN-driven telephone management
- Hundreds of patients on warfarin
- No protocol
- Lack of follow-up and compliance
- Minimal documentation

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WHERE DO I EVEN BEGIN?

- Establish the need and identify stakeholders
- Regulatory and legal considerations
- Design and set-up
- Develop protocols
- Financial planning
- Outreach
- Evaluation and reporting

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THE NEED

- Warfarin continues to have a market
- Direct oral anticoagulants (DOACs) still require monitoring
- Patient and caregiver education
- Pharmacist presence and expertise

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ADVANTAGES OF AN ANTICOAGULATION CLINIC

Patient	Institution
Point of care testing (POCT)	Specialized and continuous staff
Personalized education and understanding	Protocol standardization
Face to face contact with a healthcare professional	Data tracking
Improved communication with healthcare team	Increased efficiencies
Increased satisfaction for care	Revenue generation and cost savings

Bungard TJ, et al. Open Med. 2009 Feb 2;3(1):e16-21.; Manzoor BS, et al. Ann Pharmacother. 2017 Dec;51(12):1122-1137.

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EXPECTED CHALLENGES

- Patient push-back
- Provider resistance
- Reimbursement difficulty
- Financial considerations
- Resources

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CASE STUDY

Joint Commission is expected to arrive to the hospital for their routine audit sometime over the next year and the healthcare system has put an emphasis on ensuring compliance to national guidelines.

Providers and nursing are mostly excited for pharmacy to be involved in the new clinic, but some feel that this new initiative is not necessary.

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WHICH OF THE FOLLOWING ESTABLISHES THE GREATEST NEED FOR A PHARMACIST-RUN ANTICOAGULATION CLINIC FROM A REGULATORY STANDPOINT? (OBJECTIVES #1 & #2)

a. Ensuring compliance with National Patient Safety Goals
b. Legally pharmacists are required to manage warfarin
c. National guidelines recommend pharmacist management

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IMPROVING OUTCOMES

National Patient Safety Goals: NPSG.03.01.01: *Reduce the likelihood of patient harm associated with the use of anticoagulation therapy*

Significant data supporting improved outcomes and financial benefit

AC Forum Stewardship Program Gap Analysis

https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3_19_anticoagulant_therapy_rev_final1.pdf

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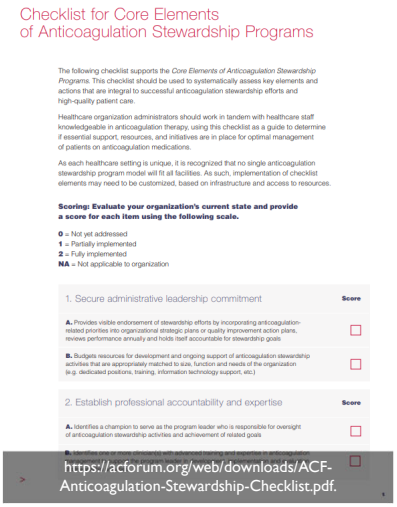
RESOURCES

Customizable checklists and gap analyses

Anticoagulation Forum


Checklist for Core Elements of Anticoagulation Stewardship Programs

The following checklist supports the *Core Elements of Anticoagulation Stewardship Programs*. This checklist should be used to systematically assess key elements and actions that are integral to successful anticoagulation stewardship efforts and high-quality patient care.

Healthcare organization administrators should work in tandem with healthcare staff knowledgeable in anticoagulation therapy, using this checklist as a guide to determine if essential support, resources, and initiatives are in place for optimal management of patients on anticoagulation medications.

As each healthcare setting is unique, it is recognized that no single anticoagulation stewardship program model will fit all facilities. As such, implementation of checklist elements may need to be customized, based on infrastructure and access to resources.

Scoring: Evaluate your organization's current state and provide a score for each item using the following scale.

0 = Not yet addressed
1 = Partially implemented
2 = Fully implemented
NA = Not applicable to organization

1. Secure administrative leadership commitment — Score

A. Provides visible endorsement of stewardship efforts by incorporating anticoagulation-related priorities into organizational strategic plans or quality improvement action plans, reviews performance annually and holds itself accountable for stewardship goals

B. Budgets resources for development and ongoing support of anticoagulation stewardship activities that are appropriately matched to size, function and needs of the organization (e.g. dedicated positions, training, information technology support, etc.)

2. Establish professional accountability and expertise — Score

A. Identifies a champion to serve as the program leader who is responsible for oversight of anticoagulation stewardship activities and achievement of related goals

https://acforum.org/web/downloads/ACF-Anticoagulation-Stewardship-Checklist.pdf.

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WHICH OF THE FOLLOWING BEST DESCRIBES THE REASON FOR DEVELOPING A PHARMACIST-DRIVEN ANTICOAGULATION CLINIC? (OBJECTIVE #1)

a. Improved outcomes for patients
b. Less need for space and resources
c. Patient willingness to come to clinic

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IDENTIFY STAKEHOLDERS

- Pharmacy leadership
- Medical leadership
- Informatics
- Pathology/Lab
- Board of pharmacy
- Financials
- Office management

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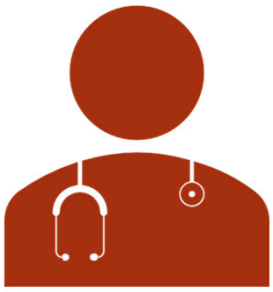
SELECT MEDICAL DIRECTOR

- Extensive anticoagulation knowledge
- Strong advocate for clinic and pharmacy
- Approachable and available
- Identify the most effective specialty for your institution
  - Cardiology
  - Vascular
  - Hematology
  - Primary care



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REGULATORY AND LEGAL CONSIDERATIONS

- Licensing of pharmacists and providers
- Collaborative drug therapy management per state law
- Ensure protocols mirror most timely national guidelines
- Liability insurance
- Establish an error reporting system
- Billing

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COLLABORATIVE PRACTICE AGREEMENT

- **Sec. 20-631. Collaborative drug therapy management agreements between pharmacists and physicians.**
  - Between 1 or more pharmacists and 1 or more physicians or APRNs
  - Written protocol-based agreement established by treating provider/pharmacist
  - Authorizes a pharmacist to implement, modify, continue, discontinue or deprescribe drug therapy, order associated laboratory tests
  - Protocol must include specific parameters
  - All pharmacist activities must be documented in the medical chart
  - Protocol must be available for inspection
  - Copy of protocol shall be filed in patient's medical record
  - Pharmacist competency required

https://law.justia.com/codes/connecticut/2022/title-20/chapter-400j/section-20-631/.

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SCOPE OF SERVICE CONSIDERATIONS

- Which medications are covered?
  - PO vs. Parenteral
  - Warfarin vs. DOACs
- What is included in a visit?
  - Medication reconciliation
  - Vital signs
  - Venous blood draws
  - Prescribing vs. Refilling
  - Dispensing
- Patient population (risk and acuity)

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DEFINE TARGET PATIENT POPULATION

	Telephone Management	In Person Management
Population	• Nursing home, ALF, SNF, etc. • Homebound • Self-managed	• Clinic patients
Advantages	• Efficient calls	• Reimbursement • Patient relationship
Challenges	• Reimbursement • Communication and coordination of care	• Finite time • Increased cost to patient

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ADDITIONAL PATIENT CONSIDERATIONS

- Indications for therapy
- INR ranges
- High risk patients
- Non-compliance

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DETERMINE STAFFING NEEDS

- Anticipate number of patients to be managed
- Hours available
- Number of staff available
- Reassess periodically

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STAFFING MODEL

Staff	Role(s)
Physician	• Chief officer • Collaborative practice agreement
Pharmacist	• Patient visits and education • POCT administration • Prescriptions • Quality control • Telephone orders and monitoring
RN	• Patient visits • Vital signs • POCT • Telephone orders and monitoring
PA/APRN	• Patient visits and education • POCT administration • Prescriptions • Telephone orders and monitoring
Pharmacy Technician	• POCT • Medication reconciliation
Administrative assistant	• Scheduling • Billing • Fax and phone transmission

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STAFFING MODEL

Staff	Pros	Cons
Physician	• Clinical and financial autonomy	• $$$ • Time restrictions
Pharmacist	• Extensive pharmacotherapy knowledge • Autonomy under CPA	• $ • Incident to billing
RN	• Able to draw venous blood samples • Vital signs and physical assessment skills	• Cannot work under CPA • Incident to billing • Training required
PA/APRN	• Clinical and financial autonomy	• $$ • Time restrictions
Pharmacy Technician	• Fairly inexpensive • POCT • Medication reconciliation	• Must work directly under a pharmacist
Administrative assistant	• Streamline logistics • Improve efficiency by preventing interruption	• Unable to cross-train

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CLINIC STAFF TASKS

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CASE STUDY

- The budget for the clinic has been established. Your director indicates that there is probably only enough allotment for 2-3 full time positions devoted to the clinic.
- Staffing duties need to be allocated accordingly to ensure that personnel have the ability to complete as many tasks within their scope as possible.
- Administrative responsibilities will likely be placed on the pharmacist to limit the need for additional resources.

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WHICH STAFF MEMBER WOULD BE MOST SIGNIFICANT TO ENSURE EMPLOYMENT/ INCENTIVE OF FOR THIS STAFFING MODEL? (OBJECTIVE #2 & #3)

a. Medical director
b. Registered nurse
c. Receptionist

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a. **Medical director**
b. Registered nurse
c. Receptionist

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RECRUITMENT

01

A well written job description will be useful in managing employees

- Make flexible to allow for changes and growth

02

Consider post graduate specialty experience

- Cardiology
- Ambulatory care
- Anticoagulation

03

Ensure transparency in duties and hours

04

Market for Fall start if possible

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SUPERVISION

Clearly establish chain of command

Designated supervisor in the clinic will:

- Field difficult patient/provider care concerns
- Address disciplinary issues
- Performance evaluations of all clinic staff
- Direct and lead staff to ensure smooth operation of clinic

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DETERMINE CLINIC HOURS

POSSIBLE WEEKEND OR EVENING HOURS TO ACCOMMODATE WORKING PATIENTS

CONSIDER COVERAGE, STAFFING LEVELS DURING VACATIONS

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DEVELOPMENT OF WRITTEN POLICIES AND PROTOCOLS

- Purpose and goals
- Scope of services
- Roles and responsibilities of patients and clinic staff
- Training and competency requirements
- Criteria for physician consultation
- Process for managing critically high INR's
- Referral process-include inclusion/exclusion criteria
- Patient educational session content and method of delivery
- Initial laboratory monitoring
- Warfarin initial and maintenance dose adjustment guidelines
- Frequency of monitoring INR guidelines
- Thromboembolic/Hemorrhagic risk assessments

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OVERALL CLINIC GOALS

Optimize SAFETY and EFFECTIVENESS of anticoagulation therapy

- Determine appropriateness of AC therapy
- Systematic and reproducible dosing
- Ongoing patient, caregiver, and provider education
- Minimize/resolve side-effects, ADRs, and drug-drug interactions

Longterm goals

- Financial benefits
- Patient satisfaction
- Healthcare efficiency

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PROTOCOL AND PROCEDURE DEVELOPMENT

- Guidelines for assessing therapy
- Documentation method and requirement
- Billing criteria and process
- Process for managing non-compliant patients
- Method for processing prescriptions
- Forms used by the clinic and/or sent to the patient
- Communication procedures
- Quality assurance
- Identification of high-risk patients and management method

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WHICH OF THE FOLLOWING PROCESSES WILL ENSURE STANDARDIZED, LEGAL AUTONOMOUS CARE BY A PHARMACIST? (OBJECTIVE #3)

a. Development and approval of a collaborative practice agreement with 1 or more providers
b. Purchase and attainment of an NPI and DEA number by each employed pharmacist
c. Requiring a PGY2 residency completed in ambulatory care by all employed pharmacists

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PROTOCOL DEVELOPMENT (PER SEC. 20-631)

- **Sec. 20-631. Collaborative drug therapy management agreements between pharmacists and physicians.**
- (1) specific...drugs to be managed by the pharmacist
- (2) the terms and conditions under which drug therapy may be implemented, modified, continued, discontinued or deprescribed
- (3) the conditions...which the pharmacist is required to notify the [provider]
- (4) the laboratory tests that may be ordered.
- All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record.
- The pharmacist shall report any encounters within the scope of the collaborative drug therapy management agreement within thirty days to the physician or advanced practice registered nurse regarding the patient's drug therapy management or document such information within a shared medical record. The collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

https://law.justia.com/codes/connecticut/2022/title-20/chapter-400j/section-20-631/.

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PROTOCOL DEVELOPMENT (PER SEC. 20-631)

Requirement	Considerations
Specific medications to be managed	• Warfarin • DOACs • LMWH • Vitamin K
Terms in which therapy is modified or implemented	• INR algorithm • Dosing protocols • Tablet formulations
Conditions requiring provider notification	• What would be constituted as critical • Non-protocol
Laboratory tests	• INR • SCr • Hepatic panel: Alb, LFTs, T.bil • CBC

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PROTOCOL LOGISTICS

- Executive body approval (e.g. P&T Committee)
- Documentation in the EMR
- Report encounters to provider within 30 days
  - EMR documentation constitutes this
- Copy of protocol in patients EMR
  - Attachment to encounter/note
  - Scanned in media section
  - Attachment to anticoagulation episode
- Hard copy available for inspection
- Ensure signatures of participants up to date

https://law.justia.com/codes/connecticut/2022/title-20/chapter-400j/section-20-631/.

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- Keep recommendations flexible
- Bridging protocols
- Reference guidelines
- Various samples available online

DOSING MONOGRAMS

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FINANCIAL CONSIDERATIONS

Determine funding source

Pharmacy vs alternative

Shared cost-centers

Create a business plan

How many patients do you expect to see?

What is the average expected revenue per patient?

Expected cost savings?

Expected costs: salaries, resources

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CASE STUDY

- The clinic will operate out of a shared cost-center by the cardiology and pharmacy department
- About 200 patient encounters are expected each month initially
- Expected revenue approximately $20,000 per month

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IDENTIFY THE MOST IMPORTANT RESOURCE TO ACQUIRE AHEAD OF STARTING PATIENT VISITS: (OBJECTIVE #2)

a. A fax machine
b. A private space
c. A white coat

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b. **A private space**
c. A white coat

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ADDITIONAL COST CONSIDERATIONS

- Computer
- Printer
- Scanner
- Fax machine
- Telephone
- Scale
- Software (Consider what is at your disposal)
- Point of Care Testing (including supplies)
- Personnel Salaries

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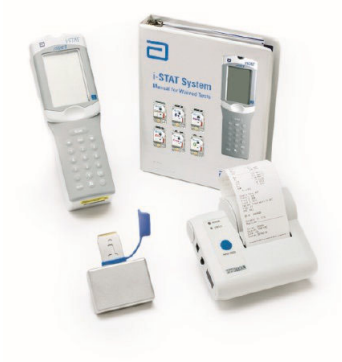

POINT OF CARE TESTS

- CLIA Certification
- Sharps container, gauze, band-aids, gloves

https://serfinitymedical.com/products/istat-pt-inr-cartridge-coagulation-prothrombin-time-for-i-stat-handheld-blood-analyzer-abbott-point-of-care-03p8924-581694edical
https://diagnostics.roche.com/global/en/products/instruments/coaguchek-xs-plus-ins-805.html system

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WHAT POSES THE BIGGEST FINANCIAL CHALLENGE FOR ESTABLISHING A PHARMACIST-RUN ANTICOAGULATION CLINIC? (OBJECTIVE #4)

a. Cost of supplies is significant
b. Lack of pharmacist reimbursement
c. Services are free for patients

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REVENUE GENERATION

- Focus on cost-savings versus revenue
- Reimbursement is inhibited by lack of provider status
- "Incident to" billing under provider
- Telephone encounters typically not reimbursed
- POCT reimbursement

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WHICH OF THE FOLLOWING STRATEGIES COULD BE UTILIZED TO MINIMIZE OVERALL CLINIC COSTS? (OBJECTIVE #4)

a. Reduce clinic hours
b. Streamline staff
c. Utilize an iSTAT meter

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FINANCIAL OPTIMIZATION STRATEGIES

- Streamline staff
- Flex hours
- Ongoing outreach
- Consider bringing in home patients periodically
- Think outside the box

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HEALTH AND SAFETY CONSIDERATIONS

- Safe finger-stick blood tests
- Glove/eye protection policy
- Sharps disposal
- Needle-stick injury procedure
- Hepatitis vaccination and antibody testing
- Safe use of liquid quality controls

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SOFTWARE CONSIDERATIONS

- Necessary entry fields
  - Goal INR range
  - Indication for therapy
  - Start/stop dates
  - Referring MD
  - Progress notes
- Dosing schedule/calendar
- Dosing calculator
- Downtime procedures
- Interface with institution, outside labs, etc.
- Data integrity
- Reports
- Patient education

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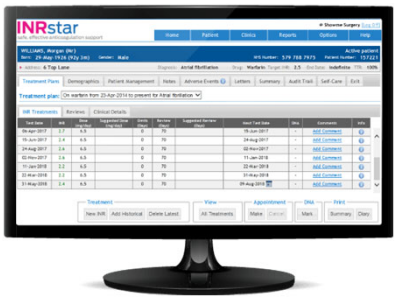
ANTICOAGULATION SOFTWARE

- Epic – Anticoagulation Navigator
  - Included if institution already has ambulatory software
- Dose Response
- Dawn AC
- Homegrown Systems



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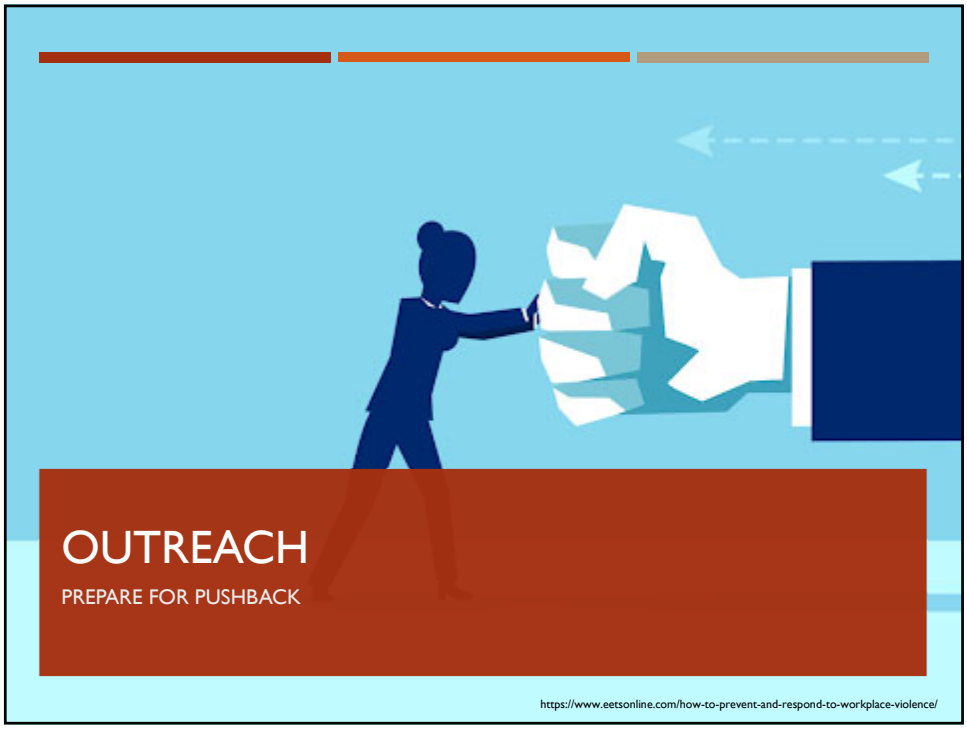

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MANAGING RESISTANCE

- Change is difficult
- Empathize with patients and providers
- Assurance of benefits ADDED
- Provide ample notice and transparency

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OPTIMIZING PATIENT REFERRALS

- Inpatient transitions of care
- Physical presence in clinic
- Provide non-anticoagulation resource when able
- Visit primary care clinics
- Inservice presentations

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CASE STUDY

- Ongoing presence in the clinic and adaptability improves patient satisfaction and brings in more patients
- Once hesitant nurses and providers are now seeking out your expertise
- Frequent reporting of ongoing outcomes has allowed for even more referrals

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WHICH OF THE FOLLOWING STRATEGIES WILL ALLOW FOR SUSTAINED FUNCTION AND IMPROVEMENT OF THE CLINIC ONCE ESTABLISHED? (OBJECTIVES #2 & #3)

a. Reducing hours once less time is needed for appointments
b. Routine evaluation and reporting of clinical outcomes
c. Transitioning majority of patients to a DOAC

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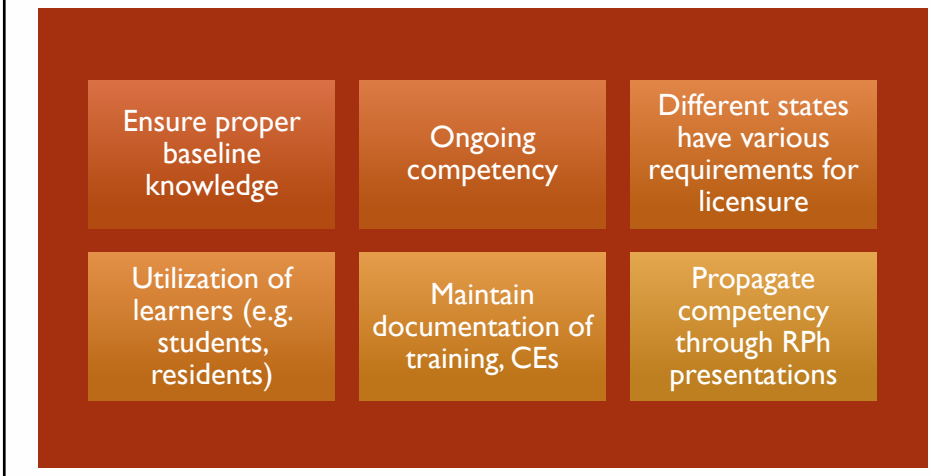

QUALITY CONTROL AND ASSURANCE: PERSONNEL

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QUALITY CONTROL AND ASSURANCE: OUTCOMES

- Periodic reports
  - Time in therapeutic range
  - Adverse effects
  - Patient satisfaction
- POCT calibration
- Protocol modifications

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AS YOU RUN REPORTS FOR THE FIRST YEAR OF SERVICE OF YOUR ANTICOAGULATION CLINIC, WHAT RESULTS DO YOU EXPECT TO SEE BASED ON PREVIOUS LITERATURE? (LO #1)

a. Decreased patient satisfaction scores
b. Increased frequency of bleeding
c. Improved time in therapeutic range

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b. Increased frequency of bleeding
c. **Improved time in therapeutic range**

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- Pharmacist-run anticoagulation clinics improve therapeutic outcomes, patient and provider satisfaction, and reduce the risk of adverse events
- Establishing a clinic requires multiple steps and a well-planned process involving a multidisciplinary team
- Legal and clinical guidance is available from a national and state level to allow for safe, standardized care by a pharmacist
- Strategies exist for generating revenue while providing a cost-savings service

TAKE HOME POINTS

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